

***Remarks***

This Amendment is in response to the Notice of Non-Complaint Amendment dated **November 15, 2007**.

Claim 28 has been amended to state that the composition has been cured only for the purpose of further differentiation claim 28 from claim 1. No new matter has been added.

***Rejections***

***35 U.S.C. §112***

Claims 13, 29, 30, 37, 42, 43, and 59-70 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly, claim the subject matter which applicant regards as the invention.

It is asserted that “[i]n claims 13 and 37, acrylated amine synergists are set forth as a species of photoinitiator. Acrylated amine synergists are not known to function as photoinitiators.” Applicants have amended claims 13 and 37 by deleting “acrylated amine synergists”. New claims 71-72 have been added which depend from claims 13 and 37 respectively. These claims are directed to the acrylated amine synergists which are known to be coinitiators for UV curable compositions. No new matter has been added.

It is asserted in the Office Action that “[t]here is no antecedent basis in claim 28 for the recitation in each of claims 29, 30, 42 and 43 of the “lubricious coating” because claim 28 sets forth a “lubricious composition”.” Applicants have amended claims 29, 30, 42 and 43 by deleting the term “coating” and adding the term –composition--.

It is asserted in the Office Action”... that claim 42 should read “A lubricious

coating on the surface of a medical device or on the surface of a component thereof obtained by applying and photocuring the lubricious composition of claim 28 on said surface”. Applicants have amended claim 42. However, as “applying and photocuring” imply method steps and the claim is directed to a composition, Applicants have alternatively amended the claim to state that the coating is “disposed” on the surface of the device or component thereof, and that the composition is “cured”. No new matter has been added.

It is asserted in the Office Action that:

With respect to claims 59 and 62-65, it is not clear whether applicant intends to claim an “ethylenically unsaturated resin” as in claim 59 or an ethylenically unsaturated monomer such as alkoxylated trimethylol propane triacrylate as in claim 64. A “resin” by definition can be a natural resin or a synthetic resin wherein the synthetic resin is the polymerization or condensation product of simpler compounds, such as an alkoxylated trimethylol propane triacrylate. Furthermore, if applicant intends to claim a synthetic resin obtained by polymerization of the triacrylate in claim 64, such resin would not be expected to be ethylenically unsaturated since the polymerization saturates the unsaturation.

Applicant disagrees.

Applicant submits that it is clear from claim 59 and claims 62-65, which depend therefrom that the term “resin” refers to those compounds, including monomers, which are employed in the composition prior to curing. These compounds can also include oligomers and prepolymers. The specification on page 4, lines 19-35 and page 5, lines 1-31 fully supports this. Furthermore, the definition of resin employed in the Office Action is a very narrow definition not often employed by those of skill in the art.

However, for purposes of expediting prosecution, Applicants have amended the claims by deleting the term “resin” and replacing it with –compound--. No new matter has been added.

Applicants respectfully request withdrawal of the rejection of claims 13, 29, 30,

37, 42, 43, and 59-70 under 35 U.S.C. §112, second paragraph.

***35 U.S.C. §102***

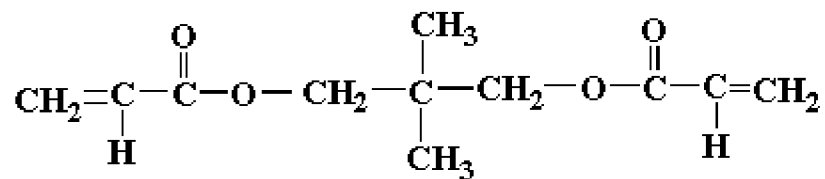
Claims 1-9, 12, 16, 17, 21-23, 27-32, 34-36 and 41-43 are rejected under 35 U.S.C. §102(b) as being anticipated by Buscemi et al (5,693,034). “Buscemi et al disclose a lubricious polymer network comprising the reaction product of a vinyl prepolymer and an uncrosslinked hydrogel retained within the reaction product so that the network exhibits greater lubricity when wet.” Office Action page 4.

Applicant traverse the rejection.

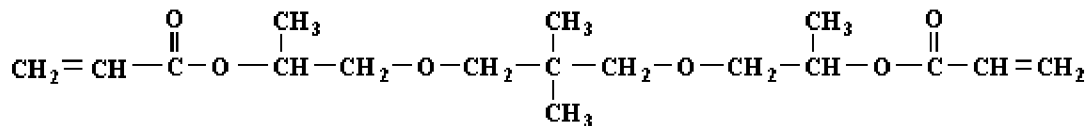
Claim 1 of the present application is directed to an embodiment of a lubricious composition including at least one polymerizable alkoxylated (meth)acrylate compound and at least one component that provide lubricity.

Buscemi et al. disclose a variety of vinyl polymers for use in formation of the lubricious polymer network disclosed therein. For example. See col. 2, lines 56-67 to col. 3, lines 1-3 including a variety of acrylates.

Alkoxylated acrylates as recited in independent claim 1 of the present invention have a different chemical structure than their corresponding acrylates. For example, neopentyl glycol diacrylate has the following chemical structure:



One example of a propoxylated neopentyl glycol diacrylate has the following chemical structure:



Therefore, the alkoxylated (meth)acrylates recited in independent claim 1 are not anticipated. Claims 2-9, 12, 16, 17, 21-23 and 27 depend from claim 1 and are not anticipated for at least the reasons that claim 1 is not anticipated.

Independent claim 28 is directed to a lubricious composition curable by actinic radiation including, among other features, a polymerizable alkoxylated (meth)acrylate. Claim 28 has been amended to correct typographical errors in the preamble and to replace “acrylate” with --(meth)acrylate-- as recited in claim 1. No new matter has been added. Claim 28 is not anticipated for at least the reasons that claim 1 is not anticipated.

Claims 29-32, 34-36 and 41-43 depend from claim 28 and are not anticipated for at least the reasons that claim 28 is not anticipated. Where appropriate, these dependent claims have also been amended to replace “acrylate” with --(meth)acrylate--. No new matter has been added.

Applicant respectfully requests withdrawal of the rejection of claims 1-9, 12, 16, 17, 21-23, 27-32, 34-36 and 41-43 under 35 U.S.C. §102(b) as being anticipated by Buscemi et al (5,693,034).

Claims 1-13, 15, 16, 22-25, 27-33, 36, 37, 39-43, 59, 60, 62-66 and 70 have been

rejected under 35 U.S.C. §102(b) as being anticipated by Burns et al (6,506,823). It is asserted that Burns et al disclose nitrocellulose based coating compositions comprising polymerizable reactive diluents, acrylated urethane and photoinitiator.”

Applicant traverses the rejection.

Applicant submits that claim 1 of the present application is directed to a lubricious composition including a polymerizable alkoxyated (meth)acrylate and at least one second component that provides lubricity.

Claim 28 also directed to a lubricious composition includes, among other features, at least one hydrophilic lubricious polymer and at least one polymerizable alkoxyated (meth)acrylate.

Claim 59 has been amended and is now directed to a catheter assembly having, among other features, a lubricious coating including at least one lubricious polymer and at least one polymerizable alkoxyated (meth)acrylate disposed on at least a portion of the catheter assembly for insertion into the body of a patient.

Applicant submits that Burns et al. is silent as to any of the compositions disclosed therein providing lubricity to a substrate or any of the four essential components of the compositions disclosed therein including the nitrocellulose, polymerizable reactive diluents having glass transitions temperatures both above and below 25° C and the acrylated urethane providing lubricity to a substrate.

In the Office Action, it is asserted that “[t]he nitrocellulose is the product of hydroxyl cellulose having only 10- 12.5% of the hydroxyl groups nitrated and thus would be expected to provide a cellulose having lubricity in the absence of evidence to the contrary.”

Office Action, page 5.

We disagree. There is no indication in the prior art that nitrocellulose, like cellulose, without further modification, provides any lubricity to a surface.

However, for purposes of expediting prosecution, claim 1 has been amended to incorporate the feature that “the at least one second component provides lubricity *when wet*.”

Claim 28 has been amended to recite that the lubricious composition includes “at least one hydrophilic polymer.”

Claim 59 has been amended and is now directed to a catheter assembly.

As to claims 1 and 28, Applicant’s preferred embodiments are those wherein the at least one second component is hydrophilic and provides lubricity when wet.

Nitrocellulose has no solubility in water. See, for example, <http://www.inchem.org/documents/icsc/icsc/eics1560.htm>, a copy of which is attached herewith. In fact, as Burns et al. disclose nitrocellulose for use in a hard lacquer for industrial finishing such as for wood finishing. See Background of the Invention and Objects of the Invention (surface hardness). It would therefore be understood that such a compound would not behave in the presence of water any differently than in its absence so as to become lubricious when wet, for example.

Therefore, claim 1, as amended, is not anticipated by Burns et al. Claims 2-13, 15, 16, 22-25 and 27 depend from claim 1 and are not anticipated by Burns et al. for at least the reasons that claim 1 is not anticipated by Burns et al.

Independent claim 28 has been amended to refer to a lubricious composition including, among other features, “at least one hydrophilic lubricious polymer and at least one polymerizable alkoxylated acrylate.

Burns et al. fails to disclose any hydrophilic polymer for use in their lacquer.

Nitrocellulose is not water soluble.

Therefore, claim 28 as amended, is not anticipated by Burns et al.

Claims 29-33, 36, 37 and 39-43 depend from claim 28 are not anticipated by Burns et al. for at least the reasons that claim 28 is not anticipated by Burns et al.

Claims 59 has been amended. Burns et al. fails to disclose the use of the lacquer composition disclosed therein on any sort of a medical device, much less a catheter assembly wherein the lubricious composition is disposed on at least a portion of the catheter assembly.

Claims 60, 62-66 and 70 depend from claim 59 and are not anticipated by Burns et al. for at least the reasons that claim 59 is not anticipated by Burns et al.

***35 U.S.C. §103(a)***

Claims 10, 11, 13, 15, 33, 37, 39, 59-70 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Buscemi et al (5,693,034) in combination with Burns et al (6,506,823).

It is asserted in the Office Action that:

With respect to claims 13, 15, 37, 39 and 59-70, it would have been obvious to one skilled in the art at the time of the invention to substitute one of the photoinitiators taught by Burns et al for the azobisisobutyronitrile disclosed by Buscemi et al. Buscemi et al teach curing by exposure to UV radiation in the presence of the azobisisobutyronitrile initiator.

With respect to claims 10, 11, 33 and 64, it would have been obvious to one skilled in the art at the time of the invention to employ ethoxylated trimethylolpropane triacrylate as an alkoxylated (meth)acrylate in the compositions taught by Buscemi et al as taught by Burns et al in analogous compositions.

Office Action, page 6, bottom to 7, first full paragraph.

Applicants disagree.

As discussed above, independent claim 1 has been amended and is now directed to a lubricious composition including a polymerizable alkoxyated (meth)acrylate and at least one second component provides lubricity when wet. Claim 28 also is directed to a lubricious composition

Claim 28 has been discussed above and recites a lubricious composition having, among other features, at least one hydrophilic lubricious polymer and at least one polymerizable alkoxyated (meth)acrylate.

Claim 59 has been amended and is directed to a catheter assembly wherein a portion of the catheter assembly includes a

**I. One of Ordinary Skill in the Art Would not be Led to Make the Combination**

**A. TSM Test Captures a Helpful Insight**

Buscemi et al. is directed to a lubricious polymer network compositions including a vinyl polymer and an uncrosslinked hydrogel retained with the reaction product such that the network exhibits a greater lubricity when wet. The invention also includes a lubricious coating for use on devices insertable within a living body. See Abstract and Summary of the Invention.

One problem discussed by Buscemi et al. is the problem associated with hydrophobic silicone in that it's coefficient of friction increases dramatically in the presence of water, plasma or blood. Background of the Invention.

Burns et al., on the other hand, disclose curable nitrocellulose based coating compositions useful as lacquers, in particular for industrial wood finishing that involves "...protective coatings for such diverse products as furniture, cabinetry, joinery, millwork,



flooring and miscellaneous coatings such as pencil lacquers, tool handle finishes, finishes for baseball bats and gun stocks.” Col. 1, lines 7-21. As shown above, nitrocellulose is hydrophobic. Furthermore, one of ordinary skill in the art would readily understand that protective coatings for wood would not be hydrophilic.

One of ordinary skill in the art would simply not be lead to combine the nitrocellulose based compositions of Burns et al. which are employed as protective coatings on wood for the purpose of improving the lubricity of a coating that is to be disposed on a device that is inserted into a living body and exposed to water, plasma or blood, regardless of what the ingredients are in the Burns et al. compositions. It simply would not be done. Not without hindsight, using Applicant’s own invention.

Even after *KSR*, there must be some reason, i.e. teaching, suggestion, motivation (TSM) test, that one of ordinary skill in the art would make the combination. “The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385, 1389 (U.S. 2007).

Applicant submits that the combination would not be made but for an impermissible hindsight reconstruction of Applicant’s invention.

## **B. Non-analogous Art**

“In order to rely on a reference as a basis for rejection of the applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. See *In re Deminski*, [796 F2D 436] 796 F.2d 436, 442, 230 USPQ 313, 315 (Fed. Cir. 1986).” *In re Oetiker*, 24

USPQ2D 1443, 1445 (Fed. Cir. 1992).

Applicant submits that Burns et al. is neither in the field of lubricious compositions used as coatings on medical devices for the purpose of reducing the coefficient of friction on the insertable portion of the device, nor is the disclosure of Burns et al. even reasonably pertinent to the problem of improving the lubricity of such a device.

There is no way that one of skill in the art would have ignored the fact that Burns et al. discloses a protective coatings for wood that are based on hydrophobic nitrocellulose and would have instead focused on individual components of the composition disclosed therein. This type of reconstruction is not permissible in establishing a *prima facie* case of obviousness. See *Panduit Corporation v. Dennison Manufacturing Co.*, 227 USPQ 337, 343 (Fed. Cir. 1985).

The Federal Circuit also stated in *Oetiker* that:

It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself. *Diversitech Corp. v. Century Steps, Inc.*, [850 F.2d 675] 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); *In re Geiger*, [815 F.2d 686] 815 F.2d 686, 687, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *Interconnect Planning Corp. v. Feil*, [774 F.2d 1132] 774 F.2d 1132, 1147, 227 USPQ 543, 551 (Fed. Cir. 1985).

*In re Oetiker*, 24 USPQ2d at 1446.

Applicant submits that it is only with impermissible hindsight, using Applicant's own invention that this combination of references would be made. The Federal circuit has stated that "...

...the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *Id.* at 999, 50

USPQ2d at 1617. That suggestion may come from, *inter alia*, the teachings of the references themselves and, in some cases, from the nature of the problem to be solved. See *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, [75 F.3d 1568] 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed.Cir. 1996); *In re Rouffet*, [149 F.3d 1355] 149 F.3d at 1355, 47 USPQ2d at 1456.

*In re Gartside*, 53 USPQ2D 1769, 1777 (Fed. Cir. 2000).

Applicant submits that a *prima facie* case of obviousness cannot be made using this combination because such a combination would not be made without using hindsight, picking and choosing elements from the prior art references that would not be combined by those of ordinary skill in the art.

Applicant respectfully requests withdrawal of the rejection of claims 10, 11, 13, 15, 33, 37, 39, 59-70 under 35 U.S.C. §103(a) as being unpatentable over Buscemi et al (5,693,034) in combination with Burns et al (6,506,823).

Claims 13, 15, 37, 39, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al (6,506,823) in view of Bae et al (5,667,735).

Applicant has discussed Burns et al. above. Burns et al. is directed to a protective composition or lacquer including, among other essential ingredients, nitrocellulose, a compound that has no solubility in water.

Bae et al. is employed for the photoinitiators disclosed therein. See page 8 of the Office Action.

However, claim 1, as amended, including the “at least one second component that provides lubricity when wet” and claim 28 as amended, including the “at least one hydrophilic lubricious polymer”, are not obvious over Burns et al. Nitrocellulose reportedly has no solubility in water leading one of skill in the art to understand that it is also neither hydrophilic nor

lubricious when wet. Not all cellulose based compounds are hydrophilic or lubricious when wet. See Applicant's own specification. Therefore, claims 1 and 28 are not obvious over Burns et al. and combining a different photoinitiator such as that disclosed by Bae et al. with Burns et al. still fails to lead one of skill in the art to the inventions of claims 1 or 28.

Claims 13 and 15 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Claims 37 and 39 depend from claim 28 and are not obvious over this combination for at least the reasons that claim 28 is not obvious over this combination.

Burns et al. fails to suggest a catheter assembly as now recited in claim 59 wherein at least a portion of the catheter assembly that is insertable into the body of a patient has a lubricious coating disposed thereon.

Combining an alternative photoinitiator as disclosed by Bae et al. fails to render claim 59 obvious. Claims 60 and 61 depend from claim 59 and are not obvious over this combination for at least the reasons that claim 59 is not obvious over this combination.

Claim 26 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al (6,506,823) in view of Wang et al (6,458,867).

Wang et al. is employed for its disclosure of an amino silane.

It is asserted in the Office Action that "[it] would have been obvious to one skilled in the art at the time of the invention to include a compound such as the amino silane taught by Wang et al. in the compositions disclosed by Burns et al in order to take advantage of the coupling properties of the silane compound." Office Action, page 9.

Applicant disagrees.

Applicant submits that Burns et al. disclose that the nitrocellulose disclosed therein is essential to the protective wood coatings disclosed therein. Nitrocellulose has no solubility in water.

Wang et al. is directed to a hydrophilic lubricious coating disposed on the inner surface of a tubular member used in medical devices, to reduce the friction between the inner surface of the tubular member and a second surface which is caused by movement. The amino silane disclosed by Wang et al. is employed to adhere the lubricious coating to the surface of the device:

In a preferred embodiment of the present invention, a silane having amino groups is utilized to adhere the hydrophilic polymer on the surface, thereby improving the retention of the lubricious coating on the device.

Col. 12, lines 24-27.

Combining the crosslinkable silane disclosed by Wang et al. with Burns et al. does not lead one of skill in the art to the invention of claim 26 because nitrocellulose is not reportedly hydrophilic and neither is crosslinked amino silane.

Furthermore, one of skill in the art would not be lead to combine the disclosure of Wang et al. with Burns et al. because Wang et al. is directed to hydrophilic coatings for medical devices.

Burns et al. is directed to protective wood coatings including the non-water soluble nitrocellulose.

Wang et al. is directed to hydrophilic lubricious coatings for use on tubular members used in medical devices to reduce friction between a surface of the tubular member and another surface. See Abstract.

Even after KSR, there must be some teaching, motivation, suggestion to combine the disclosures. “The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385, 1389 (U.S. 2007).

There is simply not any reason that one of skill in the art would look to the lubricious hydrophilic coatings of Wang et al. which are lubricious when exposed to bodily fluids in order to find substitutes for ingredients in the Burns et al. protective coatings for wood. As disclosed by Wang et al., hydrophilic lubricious coatings are difficult to retain on a surface when exposed to bodily fluids because they are hydrophilic. See col. 1, lines 58-60.

There would simply not be a readily apparent benefit to doing so. If one of skill in the art cannot implement a predictable variation, or see the benefit of doing so, the combination does not preclude patentability under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007).

Applicant respectfully requests withdrawal of the 35 U.S.C. §103(b) rejection of claim 26.

**CONCLUSION**

Claims 1-13, 15-17, 21-37, 39-43, 59-61 and 63-70 are pending in the application.

Claim 62 has been canceled without prejudice. Claims 14, 18-20, 38 and 44-58 are withdrawn from consideration as being drawn to a non-elected invention. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 28, 2007

By: /Lisa Ryan-Lindquist/  
Lisa R. Lindquist  
Registration No.: 43071

6640 Shady Oak Dr., Suite 400  
Eden Prairie, MN 55344-7834  
Telephone: (952) 563-3000  
Facsimile: (952) 563-3001